Opportunity Title: FDA Drug Safety – Medication Errors Fellowship
Opportunity Reference Code: FDA-CDER-2023-1251B

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2023-1251B

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 5/16/2023 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

CDER Office/Lab and Location: A research opportunity is available in the Division of Medication Error Prevention and Analysis I (DMEPA I), Office of Medication Error Prevention and Risk Management (OMEPRM), Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland. CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.

Research Project: Formal training will be provided at the Institute for Safe Medication Practices (ISMP) and FDA where participant will gain knowledge in Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA), and other risk-assessment tools and methods. The research project will provide hands on experience on analyzing medication error, use error reports received in the ISMP Medication Reporting Program and the FDA Adverse Event Reporting System, and the participant will gain knowledge of advanced regulatory science in assessing user interface differences between biosimilar/biosimilar interchangeable products and reference products. The mentor will aid the participant to develop the specific research methodology, guide the participant through analyzing the research findings, and apply the findings to regulatory review.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. **The appointment is for 12 months. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA**. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is

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required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should have received a bachelor's, master's, or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred Skills:

- A strong background in medication error prevention and analysis.
- A year of pharmacy residency practice in an educational and training environment is desired

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (48 👁)

Affirmation

I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)